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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,600	12/13/2004	Haruo Sugiyama	275596US96XPCT	4687

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

AUDET, MAURY A

ART UNIT	PAPER NUMBER
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1654

NOTIFICATION DATE	DELIVERY MODE
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07/02/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary

Application No.

10/517,600

Applicant(s)

SUGIYAMA ET AL.

Examiner

Maury Audet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 18, 19 and 37 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 6 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37 is/are allowed.
- 6) ☒ Claim(s) 19 is/are rejected.
- 7) ☒ Claim(s) 1-4, 18, and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7; See cont.</u> | 6) <input type="checkbox"/> Other: _____ |

IDS cont.: 05/06, 04/06, 03/06, 12/05, 09/05, 05/05, 12/04

DETAILED ACTION***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-6, 18-19, and 22, as drawn to the elected peptide of the invention (not species) of SEQ ID NO: 2, in the reply filed on 6/12/07 is acknowledged. Claim 22 has been cancelled. Claims 5-6 are withdrawn as not being drawn to the elected peptide SEQ ID NO: 2, but rather SEQ ID NO: 4, non-elected subject matter. Claims 1-4, 18-19, and 37 are examined on the merits, as drawn to the elected peptide of the invention, SEQ ID NO: 2. [Note this does not include alterations thereto, as in e.g. claims 3-4, the full-length SEQ ID NO: 2 must be present and unaltered to constitute the elected invention].

Claim Rejections - 35 U.S.C. § 112 1st Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the HLA-A24 restricted peptide (elected artificial peptide SEQ ID NO: 2) as a *cancer antigen protein*, to one or more forms of cancer [whereby it is suggested Applicant both identify/claim those forms for which this peptide may target], does not reasonably provide enablement for being a *cancer vaccine*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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Applicants have reasonably demonstrated/disclosed that the elected SEQ ID NO: 2 is a cancer antigen protein to one or more forms of cancer. However, the claims also encompass a cancer vaccine, which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "vaccine" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does the term "antigen or treat", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind, including cancer, cannot be totally cured. Absent evidence to the contrary, SEQ ID NO: 2 is not cancer vaccine for one or more cancers, but merely a cancer antigen, to one or more forms.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use the claimed composition which would function to prevent transformation of a normal cell into a tumor cell using SEQ ID NOS: 113, 118, 124-128.

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 19, it is unclear what is meant by the phrase "effective ingredient" as to SEQ ID NO: 2 in the context of a cancer vaccine. Effective in terms of serving as the vaccine to a

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cancer? Effective as an additional component/carrier, etc. e.g. for carrying (covalently) a cancer vaccine active agent to the target site.

Claim Objections

Claims 1-4, 18-19 are objected to because of the following informalities: the claims have not been amended commensurate in scope with the elected invention, namely the elected compound of the invention, peptide sequence SEQ ID NO: 2, to which the claims have only been examined as drawn thereto.

Appropriate correction is required.

Allowable Subject Matter

Claim 37, an independent claim drawn to the elected peptide of the invention, artificial peptide sequence of SEQ ID NO: 2, was not found to be reasonably taught or suggested by the prior art of record.

Conclusion

Claim 37 is allowed.

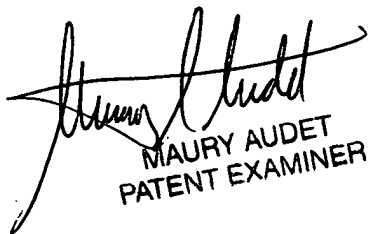
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 6/23/2007



MAURY AUDET
PATENT EXAMINER